DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-231/S-022

Colgate-Palmolive Company
Attention: Richard K. Bourne, Ph.D.
Director, Regulatory Affairs
909 River Road
P.O. Box 1343
Piscataway, NJ 08855-1343

Dear Dr. Bourne:

Please refer to your supplemental new drug application dated October 25, 2001, received October 26, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Colgate Total® Plus Whitening Toothpaste.

This "Changes Being Effected in 30 days" supplemental new drug application provides for the following:

1. Reverts the promotional statement from "12 Hour Fresh Breath Protection ....." (approved in S-021) to "Long-lasting Fresh Breath Protection...." (as originally approved in S-015).

2. Adds the term "Buildup" to the cosmetic claim "Fights tartar" so that it now reads "Fights Tartar Buildup" which was approved in S-021.

3. Adds the term "Gel" to the carton because this product contains a ratio of 80% blue gel to 20% white paste.

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (immediate container and carton labels) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-231/S-022." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Elaine Abraham, R.Ph., Regulatory Health Project Manager, at (301) 827-2293.

Sincerely,

{See appended electronic signature page}

Linda M. Katz, M.D., M. P. H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Linda Katz

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